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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/874,350

06/04/2001

Beverly S. Packard

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04/18/2006

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.

P O BOX 458

ALAMEDA, CA 94501

EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/874,350

Applicant(s)

PACKARD ET AL.

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 1-7 and 9-38 are pending.

Applicants' amendment filed on February 9, 2006 is acknowledged. Applicants' response has been fully considered. Claims 1, 3, 4, 6, 7, 13, 17, 21, 24, 32 and 35 have been amended, and claims 8 and 39-61 have been cancelled. Thus, claims 1-7 and 9-38 are examined.

Oath/Declaration

2. A substitute oath or declaration filed February 9, 2006 is acknowledged.

Sequence Listing

3. A paper copy and a computer readable form (CRF) of a substitute Sequence Listing filed February 9, 2006 is acknowledged, and CRF has been entered. Note that the sequence of SEQ ID NO:170 is the same as that of SEQ ID NO:171; and SEQ ID NO:210 is the same as SEQ ID NO:216.

Withdrawn Informalities

4. The previous objection to the specification regarding F¹ and F² in formula V is withdrawn in view of applicant's amendment to the specification, and applicant's response at page 12 of the amendment filed February 9, 2006.

Withdrawn Claim Objections

5. The previous objection to claims 1, 4, 13, 17, 32 and 35 is withdrawn in view of applicant's amendment to the claims, and applicant's response at page 12 of the amendment filed February 9, 2006.

Withdrawn Claim Rejections - 35 USC § 112

6. The previous rejection of claims 1-7 and 9-38 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 13-14 of the amendment filed February 9, 2006.

Informalities

The disclosure is objected to because of the following informalities:

7. The specification indicates the amino acid, ε-aminocaproic acid is abbreviated as Ahx or J in Table 1, however, it also indicates J is C in Table 4. Appropriate clarification is required.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-7 and 9-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 5-13 of U. S. Patent 6,037,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-7 and 9-38 in the instant application disclose a fluorogenic composition for the detection of the activity of a protease having the formula cited in claim 1, where P is a peptide having a sequence such as YVHDAPV, F¹ and F² are fluorophores, S¹ and S² are spacers, aa¹,

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aa¹⁰, aa², aa³, aa⁸, aa⁹, aa⁵, aa⁴, aa⁶, aa⁷, X and Y are defined in the claim. This is obvious in view of claims 1 and 5-13 in the patent which disclose a fluorogenic composition for the detection of the activity of a protease having the formula cited in claim 1, where P is a peptide comprising a protease binding site for the protease, F¹ and F² are fluorophores, S¹ and S² are spacers, aa¹, aa¹⁰, aa², aa³, aa⁸, aa⁹, aa⁵, aa⁴, aa⁶, aa⁷, X and Y are defined in the claim. Both sets of claims cite a fluorogenic composition for the detection of the activity of a protease having the formula, wherein P is a peptide comprising a protease binding site for the protease, e.g., YVHDAPV. Thus, claims 1-7 and 9-38 in present application and claims 1 and 5-13 in the patent are obvious variations of a fluorogenic composition for the detection of the activity of a protease, which contains a peptide having a protease binding site such as YVHDAPV.

Response to Arguments

Applicants indicate a terminal disclaimer has been submitted, however, the terminal disclaimer has not been approved because it is signed by Akira Kommriya, who is not an identified official of the organization. The statement filed under 37 CFR 3.73(b) on January 2, 2002 was signed by the president of the company, Beverly Packard. Please submit a proper terminal disclaimer.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 4-7, 16-20 and 21-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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10. Claims 21-38 are indefinite because of the use of the term “Gly-Gly-Gly-Gly (SEQ ID NO:214)”, it is not clear which sequence Gly-Gly-Gly-Gly or SEQ ID NO:214 is recited in the claim, because Gly-Gly-Gly-Gly is SEQ ID NO:211, and Fmoc-Lys-Asp-Pro-Tyr-Val-His-Asp-Ala-Pro-Val-Gly-Lys-Pro-Lys-Gly-Tyr is SEQ ID NO:214 in the sequence listing. Claims 22-38 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

11. Claims 4-7 are indefinite because of recitation of “J” in the sequences of KDPJGYVHDAPVGJPKG Y (SEQ ID NO:170) and KDPYVHDAPVGJPKG Y (SEQ ID NO:172), it is not clear what amino acid “J” represents since Table 4, which recites SEQ ID NO:170 and 172, indicates J is C, while Table 1 and Sequence Listing indicate J is ϵ -aminocaproic acid. Claims 5-7 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

12. Claim 24-27 are indefinite because of recitation of “J” or “B” in the sequences of KDBYVHDAPVPKG Y (SEQ ID NO:218), KDBGYVHDAPVGPKG Y (SEQ ID NO:219), KDBJGVHDAPVGJPKG Y (SEQ ID NO:220) and KDBJG(dY)VHDAPVGJPKG Y (SEQ ID NO:219), it is not clear what amino acid “B” represents, since Table 1 and 4 indicate “B” is α -aminoisobutyric acid (Aib), while the sequence listing defines the amino acid at the position of B being Asx in these sequences. It is also not clear what amino acid “J” represents since Table 4 indicates J is C, while Table 1 and Sequence Listing indicate J is ϵ -aminocaproic acid. Claims 25-27 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

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13. Claims 16-20 are indefinite because claim 16 has the same scope as claim 15. Claims 17-20 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

Conclusion

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



**CHIH-MIN KAM
PATENT EXAMINER**

CMK

April 11, 2006